



August 16, 2010

Mr. Douglas Wood
Acting Director
Division of Postmarket Surveillance
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Ave.
White Oak Building 66, Rm. 3114
Silver Spring, MD 20993

Dear Mr. Wood:

Arizant, Inc. (“Arizant”) is a medical device company and the pioneer of forced-air warming devices used for patient warming in the peri-operative setting. I am forwarding a copy of an anonymous MedWatch Report (the “Report”) that was received by a member of Arizant’s board of directors. Purportedly authored by an unnamed anesthesiologist, the Report was transmitted by letter under the signature of Scott Augustine, the head of a competing device manufacturer. According to Augustine’s letter, the Report has already been submitted to FDA. Nevertheless, we wanted to make sure that FDA is aware of this Report and that we take such matters very seriously.

Arizant promptly reviewed all allegations in the Report for issues that might raise compliance or patient safety concerns. Please be assured that almost every issue raised in the Report had been previously investigated by Arizant in response to Scott Augustine’s prior allegations made over a number of years. We have conducted another review and again concluded that the allegations in the Report are baseless. Nevertheless, we wanted to alert you to the Report in case you did not receive a copy and assure you that we will continue to be vigilant in our efforts to investigate all allegations brought to our attention.

By way of background, it is our belief that the Report functions as a trade complaint rather than a medical device report. As you might be aware, Scott Augustine was the former CEO of Arizant. He departed the company in 2003, and subsequently pleaded guilty to a violation of federal healthcare law. Since his departure, his actions have been antagonistic and he has engaged in substantial efforts to get Arizant to pay him for a pending patent he claims solves the alleged “deficiencies” outlined in the Report. Notwithstanding this background, we take this Report seriously and have endeavored to ensure that all allegations have been fully investigated.

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Once again, we have concluded that the allegations in the Report are without merit. We are available to discuss the allegations and answer any questions or concerns you may have at any time. Thank you.

Sincerely,

David Westlin
Chief Compliance Officer
Senior Director of Regulatory Affairs
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cc:

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LCR Michelle E. Noonan-Smith
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